



This document is scheduled to be published in the Federal Register on 11/17/2011 and available online at <http://federalregister.gov/a/2011-29700>, and on [FDsys.gov](http://FDsys.gov)

**BILLING CODE: 4163-19-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[Docket Number NIOSH-240]**

**Public Meeting and Request for Information: Carcinogen and  
Recommended Exposure Limit (REL) Policy Assessment**

**AGENCY:** The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice of public meeting and request for public comments.

**SUMMARY:** The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS) announces a public meeting to review its approach to classifying carcinogens and establishing recommended exposure limits (RELs) for occupational exposures to hazards associated with cancer. NIOSH requested initial input on these issues (including answers to five questions listed below under *Supplementary Information*), to be submitted to NIOSH Docket number 240. Written comments to this Docket will be accepted until December 30, 2011. Written

comments submitted to the docket will be used to inform NIOSH with the review and revision of the carcinogen policy and the REL policy. NIOSH has also created a new NIOSH Cancer and REL Policy Web Topic Page [see <http://www.cdc.gov/niosh/topics/cancer/policy.html>] to provide additional details about this effort and progress updates.

## **Table of Contents**

Date and Time

Place

Status

Security Considerations

Attendee and Speaker Registration

Agenda

For Registration Information Contact

Supplementary Information

I. Background

II. Matters to Be Discussed

III. Transcript

For Further Information Contact

*Date and Time:* December 12, 2011, 9 a.m.-4 p.m., Eastern Time.  
Please note that public comments may end before the time indicated, following the last call for comments. Members of the

public who wish to provide public comments should plan to attend the meeting at the start time listed.

*Place:* Hubert H. Humphrey Building, Room 800, U.S. Department of Health and Human Services (HHS), 200 Independence Avenue SW, Washington, DC 20201.

*Status:* The meeting is open to the public, limited only by the space available. The meeting space accommodates approximately 135 people. In addition, there will be an audio conference for those who cannot attend in person. There is no registration fee to attend this public meeting. However, those wishing to attend are encouraged to sign up by November 28, 2011 with the contact person in this notice.

*Security Considerations:* Due to mandatory security clearance procedures at the Hubert H. Humphrey Federal Building, in-person attendees must present valid government-issued picture identification to security personnel upon entering the building and go through an airport-type security check.

Non-U.S. citizens are encouraged to participate in the audio conferencing due to the extra clearance involved with in-person attendance. To attend in person, a non-U.S. citizen will have to

call or send an e-mail before November 28, 2011, to the contact person in this notice, and provide passport information. If clearance is received, you will be notified; otherwise, you will not be able to attend the meeting in person.

*Attendee and Speaker Registration:* Attendees are encouraged to sign up by November 28, 2011 with the contact person in this notice. Individuals wishing to speak during the meeting may sign up when registering with the contact person. Those who have not signed up to present in advance may be allowed to present at the meeting if time allows.

*Agenda:* The meeting will begin with a brief introduction by Federal officials, followed by discussions focused on each of five questions related to the NIOSH Cancer and RELs policies (See *Supplementary Information, II. Matters to Be Discussed*). The intent of the meeting is to engage stakeholders and members of the public in discussions of the relevant issues pertaining to review and assessment of NIOSH Cancer (Carcinogens) and RELs policies. Following these discussions, time has been set aside for presentations from attendees who register to speak. Each speaker will be limited to five minutes in order to maximize the number of presentations during the meeting. If all registered presentations are made before the end time, there will be an

open session to receive comments from anyone who has not signed up on the speaker registration list who may wish to speak. Open session comments will also be limited to five minutes per person. After the last speaker or at 3:50 p.m., whichever occurs first, there will be brief closing comments by Federal officials and the meeting will be adjourned.

*For Registration Information Contact:* Karen Dragon or Sherri Diana (513) 533-8611, NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226, facsimile (513) 533-8285, E-mail [nioshdocket@cdc.gov](mailto:nioshdocket@cdc.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. Background**

NIOSH and stakeholders have expressed concerns recently about limitations in the NIOSH Carcinogen Policy, prompting NIOSH to initiate a review of the carcinogen policy in 2010. A major limitation in the policy is the use of the term "Potential Occupational Carcinogen" which dates to the 1980 OSHA hazard classification for carcinogens outlined in [29 CFR 1990.103](#) and is defined as "\* \* \* any substance, or combination or mixture of substances, which causes an increased incidence of benign and/or malignant neoplasms, or a substantial decrease in the latency period between exposure and onset of neoplasms in humans or in

one or more experimental mammalian species as the result of any oral, respiratory or dermal exposure, or any other exposure which results in the induction of tumors at a site other than the site of administration. This definition also includes any substance which is metabolized into one or more potential occupational carcinogens by mammals." A major limitation of this definition is that the policy allows for only one cancer category, which is "potential occupational carcinogen." The adjective "potential" conveys uncertainty that is not warranted with many carcinogens such as asbestos, benzene, and others. This policy does not allow for classification on the basis of the magnitude and sufficiency of the scientific evidence. In contrast, other organizations, such as the International Agency for Research on Cancer (IARC) and the National Toxicology Program (NTP) allow for a more differential classification. The revision of the NIOSH Carcinogen Policy also coincides with the international realization that there is a need for more efficient and quicker means of classifying chemicals. Qualitative and semi-quantitative approaches such as hazard banding are increasingly being investigated as a means of addressing the vast numbers of unregulated chemicals. NIOSH has been in collaboration with various organizations to consider utilizing hazard banding approaches to control chemicals. This

will also be reflected in the review of the carcinogen and RELs policies.

It is anticipated that NIOSH will develop a report on the revised NIOSH Carcinogen and REL Policies to be made available in 2012. Additional information regarding NIOSH plans to assess and revise the Carcinogen and REL Policy can be found in the April 2011 NIOSH e-news at

<http://www.cdc.gov/niosh/enews/enewsV8N12.html> and on the NIOSH Cancer and REL Policy Web Topic Page [see <http://www.cdc.gov/niosh/topics/cancer/policy.html>].

## **II. Matters to Be Discussed**

Input from the public is sought on each of the five questions listed below pertaining to the NIOSH Cancer (Carcinogens) and RELs policies.

(1) Should there explicitly be a carcinogen policy as opposed to a broader policy on toxicant identification and classification (e.g., carcinogens, reproductive hazards, neurotoxic agents)?

(2) What evidence should form the basis for determining that substances are carcinogens? How should these criteria correspond to nomenclature and categorizations (e.g., known, reasonably anticipated, etc.)?

(3) Should 1 in 1,000 working lifetime risk (for persons occupationally exposed) be the target level for a recommended exposure limit (REL) for carcinogens or should lower targets be considered?

(4) In establishing NIOSH RELs, how should the phrase "to the extent feasible" (defined in the 1995 NIOSH Recommended Exposure Limit Policy) be interpreted and applied?

(5) In the absence of data, what uncertainties or assumptions are appropriate for use in the development of RELs? What is the utility of a standard "action level" (i.e., an exposure limit set below the REL typically used to trigger risk management actions) and how should it be set? How should NIOSH address worker exposure to complex mixtures?

### **III. Transcript**

A transcript will be prepared and posted to NIOSH Docket number 240 within 30 days after the meeting. Each person making a comment will be asked to give his or her name and affiliation, and all comments (including their name and affiliation) are considered to be in the public domain, and the transcript will be archived in the NIOSH Docket and posted on a public Web site.

You may submit comments, identified by docket number NIOSH-240 by any of the following methods:



- Mail: NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

- Facsimile: (513) 533-8285.

- E-mail: [nioshdocket@cdc.gov](mailto:nioshdocket@cdc.gov).

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, Room 111, 4676 Columbia Parkway, Cincinnati, Ohio 45226. A complete electronic docket containing all comments submitted will be available within 30 days of the closing date on the NIOSH web page at <http://www.cdc.gov/niosh/docket>, and comments will be available in writing by request. NIOSH includes all comments received without change in the docket, including any personal information provided.

**FOR FURTHER INFORMATION CONTACT:** T.J. Lentz, telephone (513) 533-8260, or Faye Rice, telephone (513) 533-8335, NIOSH, MS-C32, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

\_\_\_\_\_  
November 9, 2011\_\_\_\_\_

**John Howard,**

Dated

Director, National Institute for Occupational Safety and Health,  
Centers for Disease Control and Prevention.

[FR Doc. 2011-29700 Filed 11/16/2011 at 8:45 am; Publication  
Date: 11/17/2011]